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Report Highlights:

Despite lack of transparency in regulatory development and unprecedented testing requirements on imports, U.S. biotech soybeans and U.S. and domestic biotech cotton are selling at near record volumes. China is currently the largest market for U.S. agricultural biotechnology products and is the fifth largest producer of biotechnologically enhanced plants, based on acreage. A strong biotech research program and recent ratification of the Biosafety Protocol suggest biotechnology will be an integral part of China's agricultural development for the foreseeable future.

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Table of Contents

SECTION I. EXECUTIVE SUMMARY	3
SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION.....	3
Biotechnology crop production in China	3
Biotechnology crop development in China	4
Importation of biotechnology crops	4
Food aid in China.....	5
Potential for agricultural biotechnology exports to the United States.....	5
SECTION III. BIOTECHNOLOGY POLICY.....	5
Regulatory framework of agricultural policy	5
Political factors and their effect on the biotech trade.....	7
Approved biotechnology products.....	8
Biotechnology products under field trials	13
Stacked events and concurrent approvals.....	13
Labeling policy for biotechnology products.....	14
China and the Biosafety Protocol.....	14
Barriers to U.S. exports of biotechnology products.....	14
SECTION IV. MARKETING ISSUES.....	15
Market acceptance issues.....	15
SECTION V. CAPACITY BUILDING AND OUTREACH	15
U.S. Government funded outreach and capacity building programs	15
SECTION VI. REFERENCE MATERIALS	15
Reference Materials Subcategory	15

SECTION I. EXECUTIVE SUMMARY

China is the largest market for U.S. biotechnology crops. Despite problems in transparency in the development of and application of regulations, U.S. biotech soybeans and other products are selling at record highs and are forecasted to continue doing well in the future.

Details about the future of agricultural biotechnology policy in the People's Republic of China are still in doubt, but biotechnology will play an integral part of China's agricultural development. China is currently the largest market for U.S. agricultural biotechnology products (predominantly imported soy beans) and is a large producer of biotech cotton, being the fifth largest producer of biotechnologically enhanced plants based on total acreage (3.7 million hectares in 2004). China has a strong biotech research program, spending about \$44 million USD (363 million RMB) in 2003, a threefold increase over 1998 expenditures. China is set to become an even larger player in agricultural biotechnology as it has just ratified the Biosafety Protocol and will participate as a full Party in the Third Meeting of the Parties (MOPIII) in Brazil in March 2006).

While China has begun to accept more domestic and imported biotechnology products, aspects of China's regulatory system pose potential impediments for U.S. biotech products entering the market in China. These barriers include requirements that product be fully approved first from the originating country before application for approval in China, unprecedented testing for products already approved in the United States, lack specific regulatory guidelines to approve stacked events, and holding only two windows a year for acceptance of applications for new products.

Several internal and external factors seem to be influencing China's biotech policy. China has sought self-reliance in grains, adding pressure for new technologies to improve output. Bureaucratic competition seems to exist between the several ministries within the government over control of biotech policy. Trade concerns exist over countries like Japan and Korea who have threatened not to import rice and corn from China if it become a producer of biotech varieties. Finally, China has made food security and protection of domestic development of the biotech field a priority.

Several ministries are influential in biotechnology, however the Ministry of Agriculture (MOA) is the country's primary governing body over agricultural biotechnology issues. MOA Ministerial Decrees 8, 9 and 10 create the legal framework under which these products are regulated. Other government agencies, such as the General Administration on Quality Supervisions Inspection and Quarantine (AQSIQ), the Ministry of Health (MOH) and the State Environmental Protection Administration (SEPA) are also involved. SEPA is China's leading agency on the Biosafety Protocol and is the process of drafting a National Biosafety Law. There is no timeframe, however.

The U.S. government is engaged in bilateral (and interministerial) policy and technical discussions with China as well as a suite of biotechnology capacity building activities to support these discussions. Through this, the U.S. government continues to push for increased transparency in the development of regulations governing this field and look for ways to promote overall market access for U.S. biotechnology crops.

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

Biotechnology crop production in China

China has commercialized four genetically modified plants since 1997, including cotton, tomato, sweet pepper and petunia, and China is now the fifth largest producer of agricultural biotechnology crops in the world by acreage (behind the United States, Argentina, Canada,

and Brazil) at 3.7 million hectares in 2004. Pest-resistant cotton is the largest biotechnology enhanced product produced in China. The production area estimate for Bt cotton was 2.8 million hectares (MHA) in 2003, which, according to a MOA survey, increased to 3.3 MHA in 2004/2005. The result is that an estimated 60 percent of cotton produced in China in 2005 is Bt cotton, which is 8 percent higher than 2003. In the Yellow River Region, Bt varieties accounted for 95 percent, and the Yangtze River Region 70 percent. (CH5032)

There may be some unapproved varieties in production. A survey started in 2002 at the Biochemical Analysis and Experiment Center of Ho Chi Minh Agricultural University found that although corn is not a biotech product that has been approved for commercial production, 30% of the samples of corn from China were in fact genetically modified. The imported GM corn mainly contained pest and herbicide resistant genes (VM5050). China has also been criticized for allowing the production of biotech rice prior to its official approval. In Early 2005, Greenpeace alleged to have found biotech content in samples of rice gathered in southern China.

For a detailed list of agricultural biotechnology products approved for commercial production, see Section III.

Biotechnology crop development in China

China does not regularly publish lists on products undergoing development in China. In a recent presentation by Ministry of Science and Technology (MOST) officials, there are hundreds of products under development. The Chinese government has made the advancement of the biotechnology field a high priority, including it in the last three 5-year plans. China has the most sophisticated agricultural biotechnology program in the developing world.

There is no private sector development in China. Seeds in China are produced by public research institutes and universities funded by the Chinese government. Outside investment in this field was possible until 2002 when such investment became illegal. In 2003, China's government spent over 363 million RMB (about \$44 million USD) on biotechnology research, three times 1998 funding levels.

China has developed several of its own transgenic grains, but none have been commercialized. China is most notably working on the development of a rice variety that is resistant to bacterial blight known as Xa21. This would be the first biotechnology rice to be produced in China. It is expected that China will use this first biotechnology rice product as a means of paving the way for more domestic product approvals.

China recently announced the approval of a new insect resistant GM cotton crop (YinMian 2). The crop allegedly can resist bollworms and media in China have reported a 25 percent increase in yield. China's Cotton Research Institute is using transgenic technology to breed new varieties of cotton with disease resistance and better fiber quality, but no detailed results were available yet and no varieties have been commercialized. (CH5032)

Importation of biotechnology crops

China has approved 4 biotech products for import, (soy beans, corn, canola, and cotton) and is a significant importer of U.S. biotech products. In February of 2004 the Ministry of Agriculture granted safety certificates to the first round of genetically altered crops under the new regulations. Since that time, China has gone on to approve a series of biotechnology improved crops from the U.S. The current list of biotech events approved for import follows:

Imported GMOs Approved for Processing Purposes				
Crop	Trait	Developer	Event	Validity
Soybeans	Herbicide tolerance	Monsanto	GTS40-3-2	2004-2007
Corn	Herbicide tolerance	Monsanto	GA21	2004-2007
Corn	Insect resistance	Monsanto	MON810	2004-2007
Cotton	Insect resistance	Monsanto	531	2004-2009
Cotton	Herbicide tolerance	Monsanto	1445	2004-2009
Corn	Insect resistance	Monsanto	MON863	2004-2007
Canola	Herbicide tolerance	Monsanto	GT73	2004-2007
Corn	Insect resistance and herbicide tolerance	Syngenta	Bt176	2004-2007
Corn	Insect resistance and herbicide tolerance	Syngenta	Bt11	2004-2007
Corn	Insect resistance and herbicide tolerance	Dupont /Dow Agrosciences	1507	2004-2007
Corn	Insect resistance and herbicide tolerance	Bayer CropScience	T25	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Ms1Rf1	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Ms1Rf2	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Ms8Rf3	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	T45	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Topas19/2	2004-2007
Canola	Herbicide tolerance	Bayer CropScience	Oxy-235	2004-2007
Corn	Herbicide tolerance	Monsanto	NK603	2005-2008

Food aid in China

China is no longer a recipient of food aid. The final delivery of food aid from the World Food Program (WFP) was delivered to China in April of 2005 after 25 years of being an aid recipient. The WFP has determined that China can now afford to eliminate its areas of extreme poverty by itself.

Potential for agricultural biotechnology exports to the United States

China is not currently exporting biotech crops to the United States and is unlikely to be an exporter in the near-term. As such, China has not sought approval from U.S. regulators on products commercialized in China. See the list of commercialized crops for more details.

SECTION III. BIOTECHNOLOGY POLICY

Regulatory framework of agricultural policy

China's Ministry of Agriculture is chiefly responsible for approval of biotech agricultural crops for import and domestic production. Other agencies involved include China's General Administration on Quality and Supervision, Inspection and Quarantine (AQSIQ), China's State Environmental Protection Administration (SEPA), the Ministry of Science and Technology (MOST), the Ministry of Commerce (MOFCOM), and the Ministry of Health (MOH).

The biotechnology regulatory environment for agriculture outlined in the State Council's regulations *"Food and Agricultural Import Regulations and Standards; Agricultural Genetically Modified Organisms Safety Administration Regulations 2001"* (CH1056) is largely implemented by MOA under Ministerial Decrees 8, 9 and 10. These decrees: *Measures on the Safety Evaluation Administration of Agricultural GMOs, Measures on the Safety*

Evaluation Administration of Agricultural GMO Imports, and Measures on Agricultural GMO Labeling Administration (CH2002) cover import approval, domestic approval, and labeling. Labeling is covered separately in this report.

Import approvals

Biotechnology products imported into China must approve agricultural the Ministry of Agriculture. The approval process varies depending on the product's intended use (research, production or as a raw material), the safety level, the potential threat of the organism to human and animal health, and the environment.

Generally, for importation of products for raw material, which consists of the bulk of exports from the U.S. to China, Article 12 of decree 9 states that foreign company must apply for an agricultural GMO safety certificate from the Biosafety Office of Agricultural GMO. The regulations require applicants to provide a variety of materials and to have certification that the exporting country has allowed use of products and sells them in its domestic market and that they have undergone tests there showing no harm to animals, plants and the ecological environment.

Again, different conditions apply depending on the use and nature of the product to be imported. Note that products imported for production must also go through the series of field test described in the section above. Importers are encouraged to consult these regulations in detail.

Import safety certificates are issued on a time-limited basis, and renewal can be initiated one year prior to their expiration. As such, some of the first approvals that were issued 3-year safety certificates are to expire in 2007. According to the Ministry of Agriculture, the decision to renew these and subsequent certificates will focus on changes in product use over the initial certification, whether intentional or not.

Approval for domestic production

To produce biotech crops domestically in China technology providers must have passed a safety evaluation by of the National Biosafety Committee and must be issued a safety certification by the Biosafety Office of Agricultural GMO, MOA. Developing a biotech product requires the 5 following approvals (including the one above required for importation) before commercialization.

As outline below, the approval process for biotechnology products involves five steps: research, pilot experiment, environmental release, experimental production, and safety certification. Approvals are sought at the provincial or regional (groupings of a few provinces) level. After completing the 5-steps, products are eligible for safety certificates, issued by MOA's Biosafety Office of Agricultural GMO. The Biosafety Office of Agricultural GMO delegates evaluation to the application to the National Biosafety Committee. The final safety certificate is good for the province or region for which the original application was made. The 5-step approval process follows:

- (1) Application to continue research under Decree 8 including a report on experimental research already completed;
- (2) Application for a pilot experiment to begin so-called "medium testing," or test plots of less than ½ acre;
- (3) Application for testing for "environmental release." Environmental release testing takes place on less than 2 acres in the environment with specified safety precautions.
- (4) Application for production testing takes place on less than 5 acres and is the final test before seeking final approval.

- (5) The final application is for a safety certificate. The safety certificate is required for registration and approval formalities.

Other Ministries

China's State Environmental Protection Administration (SEPA) has the lead authority for negotiation and implementation of the Biosafety Protocol, which China ratified on April 27, 2005. SEPA has expressed its intent to develop an overarching Biosafety Law. SEPA has stated that work on the new biosafety law began 5 years ago and has been held up due to their importance and comprehensive nature.

The Ministry of Science and Technology (MOST) is an active participant in the development and implementation of biotechnology policy. MOST also manages a large amount of central government funds that are distributed to Chinese biotech research institutes.

The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and (their local Customs Inspection and Quarantine offices) are responsible for the nation-wide management of the inspection and quarantine for entry and exit of all GMO products. AQSIQ's Ministerial Decree 62 (CH4017) governs the steps that should be taken at customs when importing or exporting biotechnologically enhanced goods.

Political factors and their effect on the biotech trade

Factors influencing the development of biotech policy in China include:

Self-reliance: China's efforts over the last several years to become self-reliant in grain (official sources indicate self-reliant as being 85-90% self-sufficiency) have created pressure on the government to adopt more supportive biotechnology policies.

Bureaucratic Competition: Inter-agency struggles exist over the competent Ministry for regulating biotechnology in China. China's signing of the Biosafety Protocol and SEPA's interest in developing national regulations to bring itself into conformity with the Protocol continues to be a subject of debate within the government.

Trade Concerns: There is uncertainty over the impact that further GM crop commercialization would have on Chinese agricultural exports. Although the country has become a net farm product importer in recent years, it is concerned about losing export markets for non-GM crops and food products. China exports corn and rice to Korea and Japan and both have said they will stop importing if China commercializes biotech varieties of these products.

Food Security: China continues to place great emphasis on food security and developing a domestic biotechnology capacity, and wants to insure the health of its biotechnology sector as it opens its market.

Over the years, China has sent mixed signals to the global biotech industry and agricultural traders. China was very open to biotech products beginning in the mid-1980s and introduced a more restrictive approach in the late 1990s. Since a 2002 ban on foreign investment in the local seed technology industry, international biotechnology firms are not developing products in the Chinese market. However, public funding for biotechnology increased in the late 1990s, and promoting genetic engineering as a key instrument of food security policy.

Approved biotechnology products

The following is a list of food products that have been approved for commercial production in China. The list does not include the petunia events or animal vaccine events that are also approved and commercialized.

Ag GMOs approved for commercial production in China (as of March 1, 2005)

Crop	Trait	Developer	Event	Commercial production area	Validity
Cotton	Insect resistance	Monsanto	NC33B	Hebei, Shandong	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS	Bt cotton	Shanxi, Anhui, Shandong, Hubei	N/A
Cotton	Insect resistance	Monsanto	NC32B	Anhui	2000-2004
Cotton	Insect resistance	Monsanto	PM1560BG	Anhui	2000-2004
Cotton	Insect resistance	Biotech Research Institute, CAAS	SGK321	Anhui, Hebei, Henan, Shandong, Shanxi	1999-2004, 2002-2005
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK1	Anhui	2003-2007
Cotton	Insect resistance	Monsanto	DP410B	Anhui, Henan, Hubei, Hunan, Jiangsu, Jiangxi, Sichuan	2003-2007
Sweet pepper	Virus resistance	Beijing University	PK-SP01	Beijing, Fujian, Yunnan	1999-2004
Sweet pepper	Virus resistance	Beijing University	PK-TM8805R	Beijing, Fujian, Yunnan	1999-2004
Tomato	Long shelf life	Microorganism Research Institute, CAS	Da Dong No. 9	Beijing	2000-2004
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK-12	Hebei, Henan, Jiangsu, Shandong, Xinjiang	1999-2004
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK91-5	Hebei, Henan, Liaoning, Shanxi, Xinjiang	1999-2004, 2003-2007
Cotton	Insect resistance	Monsanto	DP99B	Hebei, Henan, Shandong	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS	SGK-23	Henan, Shandong, Anhui, Hebei	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS	SGK-27	Henan, Hebei, Anhui, Hubei, Shandong	2003-2007
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKz4	Henan, Shandong	2004-2008

Cotton	Insect resistance	Biotech Research Institute, CAAS	GK19	Hubei, Xinjiang	2003-2007, 2002-2005
Cotton	Insect resistance	Biotech Research Institute, CAAS	GK22	Jiangsu	2002-2005
Cotton		Microorganism Research Institute, CAS/Cotton Research Institute of Shanxi Academy of Ag. Sciences	DR409	Shanxi, Shandong, Henan	2004-2008
Cotton	Insect resistance	Monsanto	DPH37B	Anhui	N/A
Cotton	Insect resistance	Monsanto	NC20B	Henan	N/A
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK30	Shandong, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK31	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK32	Shandong, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK33	Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK34	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK35	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Rural Extension Service	GK39	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Rural Extension Service	GK44	Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Research Institute of Ag. Sciences	GK45	Henan, Hebei	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Siyang	GK51	Anhui (Huainan), Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GK52	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Dafeng Cotton Breeding Farm	GK58	Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Lunan Ag Extension Service	GKz1	Henan, Shaanxi	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Lunan Ag Extension Service	GKz2	Henan, Shaanxi	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Lunan Ag Extension Service	GKz8	Hubei, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz10	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Research Institute of Ag	GKz11	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz12	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong General Seed Station	GKz13	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hunan Cotton Science Research Institute	GKz17	Hubei, Hunan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Zhejiang Cixi Academy of Ag Sciences	GKz18	Jiangxi, Zhejiang	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Academy of Ag & Forestry Sciences	GKz19	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Keteng Cotton Co. Ltd	GKz20	Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Ag Extension Service	GKz21	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Science System Engineering Co.	GKz22	Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Nanjing Agricultural University	GKz23	Anhui, Hubei	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz25	Anhui, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz26	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Academy of Ag Sciences	GKz27	Hubei, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Cotton Research Center	GKz29	Jiangsu, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Yancheng Xinyang Ag Experiment Station	GKz32	Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hubei Huimin Seed Co.	GKz33	Hubei	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Sichuan Academy of Ag Sciences	GKz34	Sichuan	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Shandong Jiyang Luyou Cotton Institute	GKz39	Jiangsu, Shandong,	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Academy of Ag Sciences	GKz41	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	GKz (zhong) 39	Henan, Shandong, Anhui	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	RH-5	Anhui, Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Hejian Guoxin Ag Extension Service	sGK3	Hebei, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Beijing Silver Land Biotech Co.	sGK10	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Beijing Silver Land Biotech Co.	sGK11	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Henan Xinxiang Jinke Cotton Research Institute	SGK36	Hebei, Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Beijing Silver Land Biotech Co.	SGK35	Henan	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	sGK156	Anhui, Hebei, Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	sGK3017	Anhui, Hebei, Henan, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Nanjing Ag University	sGKz2	Henan, Jiangsu	

Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	sGKz4	Anhui, Hubei	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Hebei Handan Academy of Ag. Sciences	sGKz6	Hebei, Henan	
Cotton	Insect resistance	Institute, CAAS/Beijing Silver Land Biotech Co.	sGKz8	Hebei, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Jiangsu Academy of Ag Sciences	sGKz9	Anhui, Jiangsu	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKz980	Anhui, Henna,	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKz2018	Anhui, Henan, Hubei, Shandong	
Cotton	Insect resistance	Biotech Research Institute, CAAS/Cotton Research Institute, CAAS	SGKzBZ12	Anhui, Henan, Hubei, Shandong	

Biotechnology products under field trials

China allows and requires field-testing of biotechnology crops targeted for cultivation. Permission for all testing and final issuance of a safety certificate is handled by the Ministry of Agriculture's Biosafety Office or Agricultural GMO. After passing "medium testing," defined as "small-scale experiments conducted in a controlled system or under controlled conditions," China requires applicants to go through two field-tests before being approved for a safety certificate. The first test is the "environmental release" test, defined as "medium-scale experiments conducted under natural conditions with proper safety protection." This is followed by the "production test," which is carried out on a large-scale prior to production and application. Industry representatives have estimated that the process could take eight to ten years.

China does not regularly publish a list of products under development. Information from the Ministry of Science and Technology indicates that since 2001 China has initiated 333 limited field tests and 158 larged field tests of biotechnology products.

Stacked events and concurrent approvals

China's regulations currently do not include guidelines for evaluation of stacked events. China has approved cases of stacked events for local cultivation and officials have indicated that China will consider approval for importation of products with stacked events for processing on a case-by-case basis.

China also does not allow concurrent approvals in the U.S. and China. China currently requires approvals to be undertaken in the home country before approval can be sought in China.

Labeling policy for biotechnology products

China's labeling regulations, governed by Ministry of Agriculture Decree 10 (CH2002), require agricultural biotech products listed in the regulations be labeled and prohibits the importation and sale of any unlabeled or mislabeled products. The listed products are:

1. Soybean seed, soybean, soybean powder, soybean oil and soybean meal;
2. Corn seeds, corn, corn oil and corn powder;
3. Rape seed for planting, rape seed, rape oil and rape meal;
4. Cotton seed;
5. Tomato seed, fresh tomato and tomato jam.

Decree 10 states the reason for the regulation is "to strength the administration of Ag GMO labeling, standardize the selling activities of Ag GMOs, guide the production and consumption of Ag GMOs and protect consumers' right to be informed." The regulations spell out the type of labeling required as well as the specific language that is required on the individual labels.

China and the Biosafety Protocol

China's State Council ratified the Biosafety Protocol on April 27, 2005. This was not in time for the 2nd Meeting of the Parties (MOP) in Montreal, thus China participated as an observer. From the MOP-3 meetings, China will be an active member of the discussions.

As the lead authority for the Biosafety Protocol, China's State Environmental Protection Agency (SEPA) is charged with developing implementing regulations. Though SEPA has not published any new or revised laws with regard to implementation of the Protocol, SEPA has continued to state its intent to develop an overarching Biosafety Law that would take precedence over the Ministry of Agriculture's decrees regulating agricultural biotechnology.

Barriers to U.S. exports of biotechnology products

Several barriers to U.S. exports of biotechnology products to China include:

No concurrent approvals: China requires U.S. regulatory approval for a product before a product may apply for approval in China. This system makes it impossible to apply concurrently in both markets and thus causes a delay on bringing U.S. agricultural biotechnology products to the Chinese market.

Windows for submission: China has only two periods a year when companies can submit applications for new products, in March and September.

Lack of clarity on stacked events: China's regulations do not outline guidelines for evaluation of stacked events. China will consider approval for importation of products with stacked events for processing on a case-by-case basis, but the lack of clarity in this area is a concern.

Duplicative testing for imports: When goods are being approved for import into China they must first prove they have been approved by their host country. They are then required to undergo similar tests in China before being approved for a safety certificate. The extra testing in China means a delay of one to two years when bringing a product to market.

SECTION IV. MARKETING ISSUES

Market acceptance issues

China's consumers are by and large open to and acceptant of agricultural biotechnology products. Generally, there does not seem to be a negative stigma attached to biotech foods as exists in some other Asian markets. A recent nation-wide study found 60 percent or higher of respondents were willing to purchase biotech foods (including soy beans and rice) without any price discrimination. Twenty percent would only buy biotech food products when a price discount was offered. Twenty percent of respondents to the study would not accept biotech foods (with the exception of neutraceutical biotech rice) regardless of any discounts in price.

Another study found that Chinese consumers' awareness to biotech foods was low, with about 75 percent having never heard of biotech foods or having heard of them on an occasional basis. The study found that a large majority of Chinese consumers hold a favorable or neutral attitude toward biotech foods, with only 5-15 percent of urban consumers opposed to biotech foods.

These findings are consistent with a recent study by the Asian Food Information Center's study on communicating with consumers on biotechnology that found that a "majority of consumers hold an open-minded position towards biotechnology foods and did not reject them per se."

SECTION V. CAPACITY BUILDING AND OUTREACH

U.S. Government funded outreach and capacity building programs

The U.S. and Chinese governments are working closely on several fronts to assist China in its capacity to effectively and fairly handle biotechnology. The U.S.- China High-Level Biotechnology Joint Working Group (BWG) was established in July 2002 as a way to address bilateral biotechnology issues of mutual interest. To supplement the policy discussions, a technical subgroup (TWG) was established in July 2003. Together, these fora have become a constructive means to address issues of common concern.

During the 5th BWG held in Beijing on August 15-16, the U.S. and China signed a memorandum of understanding to undertake a biotechnology capacity building initiative funded by the U.S. Trade and Development Agency.

Some technical cooperation programs agreed to at the last BWG are a Technical Workshop on Safety Assessment, a Sampling/Testing Expert Exchange, a Veterinary Biologics visit in Iowa, a Biotechnology Short Course, an Insect Resistance Management Collaboration, research collaborations, APEC support, and technical meetings.

SECTION VI. REFERENCE MATERIALS

Reference Materials Subcategory

For more on studies on the marketing of biotechnology products, please see "Consumer Attitudes Toward Biotech Foods in China" by W. Lin, A. Somwaru and F. Tuan of the Economic Research Service of the U.S. Department of Agriculture and J. Huang and J. Bai of the Center for Chinese Agricultural Policy of the Chinese Academy of Sciences. The study is a selected paper prepared for presentation at the American Agricultural Economics Association Annual Meeting in Denver, Colorado on August 1-4, 2004.

A second study by the same authors titled "Consumers' Willingness to Pay for Biotech Foods in China" was prepared for presentation at the American Agricultural Economics Association Annual Meeting in Providence, RI and is dated May 12, 2005.

Yet another study on the market in China is the Asian Food Information Centre's "Communicating with Consumers on Food Biotechnology," prepared in May of 2005. The survey tracks consumer views on biotech foods from a variety of angles. The report looks at China, India, and the Philippines.

Other useful sources of information include:

USDA GAIN Reports: <http://www.fas.usda.gov/scriptsw/attacherep/default.asp>

The International Service for the Acquisition of Agri-biotech Applications: www.isaaa.org